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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,460	12/29/2005	Etienne Pouteau	112701-697	6141

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EXAMINER	
LAU, JONATHAN S	

ART UNIT	PAPER NUMBER
1623	

NOTIFICATION DATE	DELIVERY MODE
07/18/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary	Application No.	Applicant(s)	
	10/562,460	POUTEAU ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is responsive to Applicant's Amendment and Remarks, filed 24 Apr 2008, in which claim 2 is canceled; claims 1, 4 and 5 are amended to change the scope and breadth of the claim; and claim 3 is amended to better conform to US practice and to eliminate dependency from a canceled claim.

This application is the national stage entry of PCT/EP04/07092, filed 30 Jun 2004; and claims benefit of foreign priority document EP 0301486.7, filed 30 Jun 2003. This foreign priority document is in English.

Claims 1 and 3-6 are pending.

Objections Withdrawn

Applicant's Amendment, filed 24 Apr 2008, with respect to objections to the specification has been fully considered and is persuasive, because the amended specification contains appropriate section headings and the abstract ends with a period.

This objection has been **withdrawn**.

Rejections Withdrawn

Applicant's Amendment, filed 24 Apr 2008, with respect to rejection of claims 1-6 under 35 U.S.C. 112, first paragraph has been fully considered and is persuasive with regards to claims 1-3, 5 and 6, because claim 1 no longer claims preventing insulin

resistance and claim 2 is canceled. However, amended claim 4 still recites "preventing dyslipidemia", and the rejection of claim 4 is modified as recited below.

This rejection of claims 1-3, 5 and 6 has been **withdrawn**. This rejection of claim 4 is modified as recited below.

Applicant's Amendment, filed 24 Apr 2008, with respect to rejection of claims 1-4 under 35 U.S.C. 101 has been fully considered and is persuasive, because claim 1 now recites a proper process claim; claims 3 and 4 depend from claim 1 and incorporate all limitations therein; and claim 2 is canceled.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 24 Apr 2008, with respect to rejection of claims 1-5 under 35 U.S.C. 102(b) as being anticipated by Lapré et al. (US Patent 5,972,399, issued 26 Oct 1999, of record) has been fully considered and is persuasive with regard to claims 1-4, because claim 1 is amended to recite acetogenic fibers not specifically disclosed in Lapre; claims 3-4 depend from claim 1 and incorporate all limitations therein; and claim 2 is canceled. The rejection of claim 5, drawn to "a composition comprising acetogenic fibres", is modified as recited below.

This rejection of claims 1-4 has been **withdrawn**. This rejection of claim 5 is modified as recited below.

Applicant's Amendment, filed 24 Apr 2008, with respect to rejection of claims 1, 2 and 4-6 under 35 U.S.C. 102(b) as being anticipated by Eliaz (US Patent 6,462,029, issued 08 Oct 2002, of record) has been fully considered and is persuasive with regards to claims 1, 2, and 4, because claim 1 is amended to recite acetogenic fibers not specifically disclosed in Eliaz; claim 4 depends from claim 1 and incorporates all limitations therein; and claim 2 is canceled. The rejection of claims 5 and 6, drawn to "a composition comprising acetogenic fibres", is modified as recited below.

This rejection of claims 1, 2 and 4 has been **withdrawn**. This rejection of claim 5-6 is modified as recited below.

Applicant's Amendment, filed 24 Apr 2008, with respect to rejection of claims 1-3 under 35 U.S.C. 102(e) as being anticipated by Wolt et al. (US Patent 6,706,305, filed 31 Oct 2001, of record) has been fully considered and is persuasive, because claim 1 is amended to recite a method of treating and/or improving insulin resistance comprising administering a composition comprising acetogenic fibers not specifically disclosed in Wolt; claim 3 depends from claim 1 and incorporates all limitations therein; and claim 2 is canceled.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 24 Apr 2008, with respect to rejection of claim3 under 35 U.S.C. 103(a) as being unpatentable over Eliaz (US Patent 6,462,029, issued 08 Oct 2002, of record) has been fully considered and is persuasive, because claim 1 is

amended to recite acetogenic fibers not specifically disclosed in Eliaz; and claim 3 depends from claim 1 and incorporates all limitations therein

This rejection has been **withdrawn**.

The following new or modified grounds of rejections are necessitated by Applicant's Amendment, filed 24 Apr 2008, in which claim 2 is canceled; claims 1, 4 and 5 are amended to change the scope and breadth of the claim; and claim 3 is amended to better conform to US practice and to eliminate dependency from a canceled claim. Claim 3 depends from claim 1 and incorporates all limitations therein, including changes to the scope and breadth of the claim. Claim 6 depends from claim 5 depends from claim 1 and incorporates all limitations therein, including changes to the scope and breadth of the claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating and/or improving insulin resistance for increasing insulin sensitivity or treating dyslipidemia, does not reasonably provide enablement for preventing dyslipidemia. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use or make the invention commensurate in scope with these claims.

The Applicant's attention is drawn to *In re Wands*, 8 USPQ2d 1400 (CAFC1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) The nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

Nature of the invention: A method for treating and/or improving insulin resistance, increasing insulin sensitivity or preventing dyslipidemia comprising administering said composition.

The state of the prior art: Prevent is defined as "keep from happening or arising; make impossible". See provided definition of prevent (definition of prevent, WordNet, cited in PTO-892). There is no prior art disclosing making dyslipidemia impossible.

The relative skill of those in the art: The relative skill of those in the art is high.

The predictability or unpredictability of the art: The lack of any prior art disclosing making dyslipidemia impossible means that one skilled in the art cannot predict the usefulness of a product or method to make dyslipidemia impossible. Therefore the claimed invention is unpredictable.

The Breadth of the claims: The scope of the claims specifically includes prevention of dyslipidemia.

The amount of direction or guidance presented: The specification speaks generally about the effect of treatment, such as decreased insulin sensitivity, and "that these effects tend to persist for some time after treatment has ceased." See instant specification, page 11, lines 17-20.

The presence or absence of working examples: The only working examples provided are directed towards treating and/or improving insulin resistance or increasing insulin sensitivity. For example, see instant specification, examples 1 and 2 spanning pages 9 through 11.

Note that lack of working examples is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art such as prevention of dyslipidemia. See MPEP 2164.

The quantity of experimentation necessary: In order to practice the invention with the full range of all possible preventive methods beyond those known in the art, (such as treating and/or improving insulin resistance) one skilled in the art would undertake a novel and extensive research program to show that the treatment method made dyslipidemia impossible. Because this research would have to be exhaustive, and because it would involve such a wide and unpredictable scope of treatment methods, it would constitute an undue and unpredictable experimental burden.

Genentech, 108 F.3d at 1366, sates that, "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion." And "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable."

Therefore, in view of the Wands factors, as discussed above, particularly the breadth of the claims, Applicants fail to provide information sufficient to practice the claimed invention for prevention of dyslipidemia.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Amended claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Lapré et al. (US Patent 5,972,399, issued 26 Oct 1999, of record).

Lapré et al. discloses a food with a coating that comprises a polysaccharide that reduces the core's glycemic response (column 6, lines 45-47), wherein the polysaccharide is preferably pectin (column 7, line 65-66), an acetogenic fiber, and administering the food for treating individuals suffering from diabetes and hypoglycemia (column 7, lines 10-11). Lapré et al. discloses that the method of treating diabetes disclosed is a method of treating insulin resistance (column 4, lines 1-5), meeting limitations of instant claim 5.

Response to Applicant's Remarks:

Applicant's Amendment and Remarks, filed 24 Apr 2008, have been fully considered and not found to be persuasive.

Applicant asserts that Lapre does not teach or suggest the coating can treat and/or improve insulin resistance, but rather is directed to the properties of the food with a coating. However, Lapre discloses said food to treat diabetes characterized by insulin resistance, "In contrast, in Type 2 or non-insulin dependent diabetes, the pancreas is producing insulin, although it may not be doing so at normal levels. Although insulin is present, blood glucose levels are still abnormal because the body does not respond to it. However, the cause of this insulin resistance is presently unknown." (spanning column 3, lines 66-67 and column 4, lines 1-5) and "A related disease, hypoglycemia, is caused by excessive circulating insulin. This is normally a result of an accidental overdose of insulin by a diabetic. This excess insulin results in a lowering of the blood glucose level." (column 4, lines 10-15). The instant specification does not specifically define what "treating" means, therefore broadly interpreted the method disclosed by Lapre is disclosed to be known for treating insulin resistance.

Applicant points out the distinction between insulin resistance and diabetes. However, as recited above, it is Lapre that equates the two, not an assertion by the Examiner. There is no limitation in the instant claims excluding the treatment of diabetes in treating insulin resistance.

Amended claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Eliaz (US Patent 6,462,029, issued 08 Oct 2002, of record).

Eliaz discloses a modified pectin used alone or in combination (spanning column 3, line 67 and column 4, line 1) in a pharmaceutical composition (column 3, lines 53-54).

Pectin is an acetogenic fiber. Eliaz discloses the use of the composition to affect glucose tolerance (column 2, lines 52-57), a method of treating insulin resistance, meeting limitations of instant claim 5. Eliaz discloses a dosage level of 5-1500 mg per kg body weight (column 3, lines 55-59), anticipating the ranges in instant claim 6.

Response to Applicant's Remarks:

Applicant's Amendment and Remarks, filed 24 Apr 2008, have been fully considered and not found to be persuasive.

Applicant remarks that Eliaz is drawn to the treatment of obesity, hypercholersterolemia and diabetes. However, as recited above, Eliaz discloses the use of the composition to affect glucose tolerance, "Kimura et al. discloses that the study revealed that the natural sodium alginate and two of the three modified sodium alginates enhanced cholesterol secretion and inhibited blood glucose levels from rising after glucose administration. The authors noted that the results suggest that the effects of natural sodium alginate and AG-5 and AG-10 on cholesterol excretion and **glucose tolerance** may be due to inhibition of cholesterol and glucose adsorption from the small intestine by gelling of free alginic acid converted in the stomach and that these alginates can be used in the treatment/prevention of obesity, hypercholesterolemia and diabetes." (column 2, lines 45-55). As evidenced by Bergman et al. (Jounal of Clinical Investigation, 1987, 79, p790-800, cited in PTO-892), glucose tolerance is a measurement of insulin sensitivity, or conversely insulin resistance is a component of glucose intolerance (page 790, left column, paragraph 1-2), considered to be an equivalence. The instant specification does not specifically define what "treating"

means, therefore broadly interpreted the method disclosed by Eliaz of affecting glucose tolerance is a method of treating the insulin resistance.

Applicant points out the distinction between insulin resistance and diabetes. However, as recited above, it evidenced by Lapre that the two are equated, not an assertion by the Examiner. There is no limitation in the instant claims excluding the treatment of diabetes in treating insulin resistance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended claims 1, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lapré et al. (US Patent 5,972,399, issued 26 Oct 1999, of record) in

view of Felter et al. (entry for wild carrot, King's American Dispensatory, 1898, cited in PTO-892).

Lapré et al. discloses a food with a coating that comprises a polysaccharide that reduces the core's glycemic response (column 6, lines 45-47), wherein the polysaccharide is preferably pectin (column 7, line 65-66), meeting limitations of instant claim 1. Lapré et al. discloses administering said food for treating individuals (column 7, lines 10-11), meeting limitations of instant claim 5. Lapré et al. discloses the food is preferably 0.1-5% by weight pectin (column 9, lines 41-44), meeting limitations of instant claim 3. Lapré et al. discloses that the method of treating diabetes is the method of treating insulin resistance (column 4, lines 1-5), meeting limitations of instant claim 1. Lapré et al. discloses a method of treating hypoglycemia which is a method of treating sensitivity to excessive circulating insulin (column 4, lines 12-14), meeting limitations of instant claim 4.

Lapré et al. does not specifically disclose the pectin carrot pectin.

Felter et al. teaches pectin is found universally scattered over the vegetable kingdom in many fruits, roots, etc., and may be obtained from the juice of all fruits by the same process (page 3, paragraph 3). Felter et al. teaches pectin is also obtained from the juice of carrot root (page 2, paragraph 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the invention of Lapre with the teaching of Felter of the equivalence of pectins such as carrot pectin. It would have been obvious to one of ordinary skill to substitute equivalents known for the same purpose, such as the implicit

teaching of Felter et al that pectin and carrot pectin are known equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious, see MPEP 2144.06 II.

Claim 1 and 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eliaz (US Patent 6,462,029, issued 08 Oct 2002, of record) in view of Felter et al. (entry for wild carrot, King's American Dispensatory, 1898, cited in PTO-892).

Eliaz discloses a modified pectin used alone or in combination (spanning column 3, line 67 and column 4, line 1) in a pharmaceutical composition (column 3, lines 53-54), meeting limitations of instant claim 1. Eliaz discloses the use of the pectin composition to affect glucose tolerance (column 2, lines 52-57), a method of treating insulin resistance. Eliaz discloses the use of the modified pectin administered with excipient, specifically in the form of a gelatin capsule (column 5, lines 33-34 and 36-38).

Eliaz does not specifically disclose the pectin carrot pectin. Eliaz does not specifically disclose a composition wherein the amount of acetogenic fiber is in the range of from 0.2 to 90% by weight of the composition.

Felter et al. teaches pectin is found universally scattered over the vegetable kingdom in many fruits, roots, etc., and may be obtained from the juice of all fruits by the same process (page 3, paragraph 3). Felter et al. teaches pectin is also obtained from the juice of carrot root (page 2, paragraph 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the invention of Eliaz with the teaching of Felter of the equivalence

of pectins such as carrot pectin. It would have been obvious to one of ordinary skill to substitute equivalents known for the same purpose, such as the implicit teaching of Felter et al that pectin and carrot pectin are known equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious, see MPEP 2144.06 II. Further, it would have been obvious to one of ordinary skill in the art at the time of the invention to formulate the modified pectin composition of Eliaz wherein the amount of acetogenic fiber is in the range of from 0.2 to 90% by weight of the composition. It is well-known practice in formulation of pharmaceuticals such as a gelatin capsule to optimize the amount of excipient in a pharmaceutical with a reasonable expectation of success. Therefore a gelatin capsule wherein the amount of modified pectin is in the range of from 0.2 to 90% by weight of the pharmaceutical composition as a result of routine optimization would have been obvious to one of ordinary skill in the art at the time of the invention.

Conclusion

No claim is found to be allowable.

Applicant's amendment necessitated the new and modified ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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